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FOLEY AND LARDNER LLP  
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EXAMINER
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KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/668,322

Applicant(s)

SAVIDAN ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-36 is/are pending in the application.
- 4a) Of the above claim(s) 10-24, 27-30 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-26, 31-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Newly submitted claims 27-30 and 33-36 correspond to nonelected group II, as detailed in the restriction requirement mailed 21 June 2005; they, along with nonelected claims 10-24, are withdrawn from consideration as being drawn to nonelected groups.
2. This application contains claims 10-24, 27-30 and 33-36 drawn to an invention nonelected with traverse in the response filed 10 August 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Because the Notice of Non-Compliant amendment mailed 10 March 2006 was withdrawn on 23 March 2006, no negative patent term will accrue from it. This is not the case, however, for the Notice of Non-Compliant amendment mailed 17 May 2006.
5. The drawings filed 2 March 2006 are objected to nothing can be made out in Fig 4A-D.
6. The objection to claims 8-9 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim is withdrawn in light of Applicant's cancellation of the claims.
7. The objection to claims 1-7 because of informalities is withdrawn in light of Applicant's cancellation of the claims.
8. The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's cancellation of the claims.

9. The rejection of claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Pessino et al (1998, Hereditas 128:153-158) is withdrawn in light of Applicant's cancellation of the claims.

10. The rejection of claims 1-5 under 35 U.S.C. 102(a) as being anticipated by Grimanelli et al (1998, Heredity 80:33-39) is withdrawn in light of Applicant's cancellation of the claims.

11. The rejection of claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Pessino et al (1997, Theor. Appl. Genet. 94:439-444) is withdrawn in light of Applicant's cancellation of the claims.

12. The rejection of claims 1-3 under 35 U.S.C. 102(e) as being anticipated by Hanna et al (US Patent 5,811,636, filed September 1995) is withdrawn in light of Applicant's cancellation of the claims.

13. The rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Leblanc et al (1995, Theor. Appl. Genet. 90:1198-1203) is withdrawn in light of Applicant's cancellation of the claims.

14. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Kindiger et al (1996, Genome 39:1133-1141) is withdrawn in light of Applicant's amendment of the claims.

15. The rejection of claims 1-6 under 35 U.S.C. 102(e) as being anticipated by Kindiger et al (US Patent 5,710,367, filed September 1995) is withdrawn in light of Applicant's cancellation of the claims.

***Claim Rejections - 35 USC § 112***

16. Claims 26 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrases “identifying a nucleotide segment conferring diplosporous development in a plant specie” and selecting an orthologous segment in said plant species” in claim 26 and the phrases “identifying a nucleotide segment conferring apomictic development in a plant specie” and selecting an orthologous segment in said plant species” in claim 32.

The only recitation in the specification for cloning orthologous genes limits the process to dosing so in Gramineae (pg 7, lines 4-7 and 18-27, and pg 8, lines 2-17).

Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

17. Claims 25-26 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is modified from the rejection set forth in the Office action mailed 2 September 2005, as applied to claims 1-7. Applicant’s arguments filed 2 March 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to a method for mapping and cloning a nucleotide segment conferring apomixis from any plant species.

The instant specification, however, only provides discussion of mapping RFLP markers (umc28, csu68, umc38, umc71, umc134 and umc62) to *Apo* (apomeiosis) in *Tripsacum* (pg 14-17); mapping 2 RFLP markers (csu68 and cdo202) to *el* (*elongate*) in maize (pg 17-21); transposon tagging the *elongate* locus (pg 19 and 21); and a start at walking to *elongate* (pg 23-26).

The instant specification fails to provide guidance for the sequences of most of the RFLP markers used in the specification, or for any RFLP markers that identify other apomixis genes. The specification fails to provide guidance for which plant species have genes orthologous to maize apomixis and diplospory genes.

As of August 2006, 8.5 years after the filing of the instant application, there were no reports in the art of the cloning of any maize apomixis and diplospory genes by the claimed method or any other, indicting that the instant method is not enabled.

Given the claim breath, state of the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

Applicant urges that RFLP mapping may be used to identify Gramineae sequences in *Tripsacum* and maize, and the specification did so with publically available RFLP markers (response pg 7-8).

This is not found persuasive. No maize apomixis and diplospory genes have been cloned to date by RFLP mapping or any other method. Only umc28, csu68 and umc62 appear to be in the prior art. Applicant fails to provide evidence that the other RFLP markers were publicly available at the time of filing. Applicant also fails to teach RFLP markers that identify apomixis genes other than *elongate* and *Apo*, and fails to teach transposon tagging *Apo*.

Applicant urges that the number of plant species tested is not relevant, as every plant species in which the claimed invention finds applicability need not be disclosed (response pg 8).

This is not found persuasive. Claims 26 and 32 are drawn to cloning orthologous genes in plant species other than maize. What plant species have genes orthologous to maize apomixis and diplospory genes?

Applicant urges that *ell* is a recessive meiosis mutation that results in non-reduced gametophytes, citing Spillane (response pg 8).

This portion of the rejection is withdrawn.

18. Claims 25-26 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 September 2005, as applied to claims 1-7. Applicant's arguments filed 2 March 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to use of a multitude of nucleic acids that map mutations would be "orthologous to genes involved in apomixis", including mutations that are responsible for diplospory in *Tripsacum*. Applicant does not describe any nucleic acids encompassed by the claims, and the structural and functional features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the sequences are not described, the method of using the sequences to map mutations would be “orthologous to genes involved in apomixis” is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that the specification provides written support for nucleotide segments conferring an apomictic phenotype and methods for producing an apomictic phenotype in a plant; the specification discloses molecular markers, including umc28, csu68 and umc62 that can be used to identifying orthologous sequences in another plant species (response pg 9).

This is not found persuasive. The specification does not describe the structural features of any nucleotide segment that confers an apomictic phenotype in a plant. The specification also fails to describe RFLP markers that identify apomixis genes other than *elongate elongate* and *Apo*. The specification also fails to describe which plant species have genes orthologous to maize apomixis and diplospory genes.

Applicant urges that the specification provides a detailed method for using the markers to identifying nucleic acids conferring apomictic development, citing Example 2 (response pg 9-10).

This is not found persuasive. Example 2 only describes the mapping of *elongate* and *Apo* and transposon tagging. None of this describes the cloning of any gene responsible for apomictic in maize or any other plant.



Art Unit: 1638

Applicant urges that they need not provide structural and functional features that distinguish all such nucleic acids from other nucleic acids; all that is necessary is that the specification provide written support for identifying a nucleotide segment conferring apomictic development by using the illustrative markers (response pg 10).

This is not found persuasive. The starting materials used in the claimed methods, that is RFLP markers that identify apomixis genes other than *elongate* and which plant species have genes orthologous to maize apomixis and diplospory genes, are not described within the full scope of the claims.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

See *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC 2004) at page 1894:

Rochester also attempts to distinguish Fiers, Lilly, and Enzo by suggesting that the holdings in those cases were limited to composition of matter claims, whereas the '850 patent is directed to a method. We agree with the district court that that is "a semantic distinction without a difference." Univ. of Rochester, 249 F. Supp. 2d at 228. Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment."

### ***Claim Rejections - 35 USC § 103***

19. Claims 25-26 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kindiger et al (US Patent 5,710,367, filed September 1995). The rejection is modified from the rejection set forth in the Office action mailed 2 September 2005, as applied to claims 1-7, due to

Applicant's amendment of the claims. Applicant's arguments filed 2 March 2006 have been fully considered but they are not persuasive.

The claims are drawn to a method comprising mapping a locus common to *Tripsacum* and maize, wherein the locus confers diplospory or apomixis, cloning the gene, and verifying it confers diplospory or apomixis by creating and analyzing a loss-of-function mutation.

Kindiger et al used RFLPs, including csu68, and RAPDs to map mutations responsible for diplospory in an apomictic form in maize-*Tripsacum* hybrids (column 12, lines 4-33; column 19, lines 17-63; claim 7, Fig. 3). Kindiger et al also tagged a mutation with the Mu transposon, thus creating a loss-of-function mutation (column 12, line 42, to column 13, line 22; column 20, lines 49-58). Kindiger et al do not disclose cloned genes that confer apomixis development in maize.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of mapping and transposon tagging mutations linked to apomixis as taught by Kindiger et al to clone the gene linked to csu68 (*elongate*). One of ordinary skill in the art would have been motivated to do so because of the suggestion of Kindiger et al to do so (column 12, line 42, to column 13, line 22). One of skill in the art would complement the mutation with the cloned gene to confirm that the gene restores the function to the plant. One of skill in the art would also use the cloned gene to clone genes from other plants, given the economic advantages of having apomictic crop plants.

Applicant urges that even if it would be obvious to transposon tag a gene, Kindiger would not render the instant invention obvious because Kindiger does not teach or suggest identifying

and cloning a sequence conferring apomixis by creating and analyzing a loss-of-function mutation (response pg 12-13).

This is not found persuasive for the reasons indicated above.

20. Claims 25-26 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leblanc et al (1995, Theor. Appl. Genet. 90:1198-1203).

The claims are drawn to a method comprising mapping a locus common to *Tripsacum* and maize, wherein the locus confers diplospory or apomixis, cloning the gene, and verifying it confers diplospory or apomixis by creating and analyzing a loss-of-function mutation.

Leblanc et al used RFLPs (umc28, csu68 and umc62) to map mutations responsible for diplospory in an apomictic form in a maize-*Tripsacum* hybrid (pg 1199-1202). Leblanc et al do not disclose cloned genes that confer apomixis development in maize or creation of a loss-of-function mutation.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of mapping mutations responsible for diplospory as taught by Leblanc et al, to clone the genes linked to the mutations. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Leblanc et al to clone the gene (pg 1199, left column, paragraph 1). One of skill in the art would complement the mutation with the cloned gene to confirm that the gene restores the function to the plant. One of skill in the art would also use the cloned gene to clone genes from other plants, given the economic advantages of having apomictic crop plants.

Art Unit: 1638

*Conclusion*

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.

August 25, 2006



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER